K011028

510(K) SUMMARY

Pursuant to 510(i) of the Federal Food, Drug, and Cosmetic Act, as Amended.

Company Name:	Sulzer Dental Inc.
Address:	1900 Aston Avenue, Carlsbad, CA 92008-7308
Telephone Number:	760-431-9515
Registration Number:	2023141
Contact Person:	Diana Smith
Date Summary Prepared:	March 15, 2001
Classification Name:	Implant, Endosseous (76DZE)
Common/Usual Name:	Dental Implant System
Device Trade Name:	Screw-Vent Dental Implant System

The primary device used for comparison in this summary is Sulzer Dental's existing Paragon Dental Implant System. All implant systems are manufactured in the same facility located in Carlsbad, California.

1. **Intended Use:** (The statements of intended use are identical.)

   Sulzer Dental's implant systems are designed for use in edentulous mandibles or maxillae for attachment of complete denture prostheses, or as a terminal or intermediary abutment for fixed or removable bridgework, or as a freestanding single tooth replacement. The use of the 4.7mm and 6.0mm implant is recommended when the quantity and density of bone would dictate the use of an implant larger than 4.0mm.

2. **Description:**

   Screw-Vent implants are available with an HA selective surface or a selective roughened surface. They are available in 3.3mm, 3.7mm, and 4.7mm diameters and lengths of 8, 10, 13, and 16mm. The Tapered Screw-Vent implants are available with an HA selective surface or a machined/roughened surface. They are available in 3.7mm, 4.7mm, and 6.0mm diameters and lengths of 8, 10, 13, and 16mm. All implants have an internal hex connection and are fabricated from titanium alloy. The implants are all provided sterile.

3. **Technological Characteristics:**

   There has been a modification to the Screw-Vent implant with the addition of a tapered body implant. This design will provide the implant with self-tapping capabilities. The implant/abutment interface remains unchanged. There has been no change to the implant materials or to the implant/abutment interface.

4. Comparison Analysis:

The overall design of the Screw-Vent implants are identical to the predicate implants. See **Table 1** below for a comparison of the Screw-Vent implants and the predicate devices.

Feature	Screw-Vent Implants	Predicate Implants
Implant Body Geometry	Screw Type Endosseous Implants	Screw Type Endosseous Implants
Implant Lengths	8, 10, 13, 16mm	8, 10, 13, 16mm
Implant Diameters	Screw-Vent: 3.3, 3.7, and 4.7mm Tapered Screw-Vent: 3.7, 4.7, and 6.0mm	3.3mm, 3.7mm, 4.7mm
Implant Body Material	Titanium Alloy	Titanium Alloy
Implant/Abutment Interface	Internal Hex Connection	Internal Hex Connection
Manufacturing Site	Carlsbad, California	Calabasas Hills, California
HA Coating	Available on Some Designs	Available on Some Designs
Selective Roughened Surface	Available on Some Designs	Not available
Sterile	Yes	Yes

Table 1: Summary of Comparison

(i) For submission claiming substantial equivalence to a device which has been classified into class III under section 513(b) of the act:

(1) Which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990: and

(2) For which no final regulation requiring premarket approval has been issued under section 515(b) of the act, a summary of the types of safety and effectiveness problems associated with the type of devices being compared and a citation to the information upon which the summary is based (class III Summary). The 510(K) submitter shall also certify that a reasonable search of all information known or otherwise available about the class III device and other similar legally marketed devices has been conducted (Class III Certification), as described in Sec. 807.94.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2001

Ms. Diana Smith
Regulatory Affairs Associate
Sulzer Dental, Incorporated
1900 Aston Avenue
Carlsbad, California 92008-7308

Re: K011028
Trade/Device Name: Screw-Vent Dental Implant System
Regulation Number: 872.3640
Regulatory Class: III
Product Code: DZE
Dated: April 4, 2001
Received: April 5, 2001

Dear Ms. Smith:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Rebecca Cecconi-Fox

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K011028

510(K) Number (if known): K011028

Device Name: Screw-Vent Dental Implant System

Indications for Use:

Sulzer Dental Implant Systems are designed for use in edentulous mandibles or maxillae for attachment of complete denture prostheses, as a terminal or intermediary abutment for fixed or removable bridgework, or as a freestanding single tooth replacement. The use of the 4.7mm or 6.0mm implant is recommended when the quantity and density of bone would dictate the use of an implant larger than 4.0mm.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011028